



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

[Docket No. FDA-2013-N-0002]

New Animal Drugs; Change of Sponsor's Name and Address; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name and address from Purina Mills, Inc., to Purina Nutrition LLC, and a change of sponsor for a new animal drug application (NADA) from Land O'Lakes Purina Feed LLC to Purina Nutrition LLC. The regulations are also being amended to reflect that Zoetis Inc. is a sponsor of approved NADAs.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240-276-8300, email: steven.vaughn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166-6812, has informed FDA that it has changed its name and address to Purina Nutrition LLC, 1080 County Road F West, Shoreview, MN 55126-2910. Land O'Lakes Purina Feed LLC, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 118-509 for Pasture Gainer Block 37 R350 and Pasture Gainer Block 20 R350 to Purina

Nutrition LLC. Accordingly, the Agency is amending the regulations in 21 CFR parts 510 and 558 to reflect the change of name and address and the transfer of ownership.

In addition, Zoetis Inc. is a sponsor of approved NADAs. At this time, FDA is amending 21 CFR 510.600 to add entries for this firm.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 558 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. In § 510.600, in the table in paragraph (c)(1), remove the entry for "Land O'Lakes Purina Feed LLC" and "Purina Mills, Inc.", and alphabetically add entries for "Purina Nutrition LLC" and "Zoetis Inc."; and in the table in paragraph (c)(2), remove the entry for "066071", revise the entry for "017800", and numerically add an entry for "054771" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Purina Nutrition LLC, 1080 County Road F West, Shoreview, MN 55126-2910	017800
* * * * *	
Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	054771
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
017800	Purina Nutrition LLC, 1080 County Road F West, Shoreview, MN 55126-2910
* * * * *	
054771	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007
* * * * *	

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.355 [Amended]

4. In § 558.355, paragraph (f)(7)(iii)(a), remove "066071" and in add its place "017800".

Dated: May 8, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

[FR Doc. 2013-11283 Filed 05/10/2013 at 8:45 am; Publication Date: 05/13/2013]